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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,015 08/23/99 KORTH

C DT-3073

EXAMINER
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HM22/0308

DAVID TOREN  
BROWN & WOOD  
ONE WORLD TRADE CENTER  
NEW YORK NY 10048-0557

WINKLER, J	
ART UNIT	PAPER NUMBER

1648  
DATE MAILED:

03/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/380,015	Applicant(s) KORTH ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12 and 14-18, drawn to monoclonal antibodies and hybridoma cells.

Group II, claim(s) 13, drawn to an anti-idiotypic antibody.

Group III, claim(s) 19, drawn to a phage display system containing the coding sequence of a monoclonal antibody.

Group IV, claim(s) 20-23, 29, drawn to recombinant prion protein.

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Group V, claim(s) 24-27, drawn to a method of producing a hybridoma cell line expressing monoclonal antibodies against prion proteins.

Group VI, claim(s) 28, drawn to a method of producing an expression vector for prion proteins.

Group VII, claim(s) 30-34, drawn to an immunological detection method and a test kit.

Group VIII, claim(s) 35 and 36 drawn to a method of preventing prion disease and a pharmaceutical preparation using monoclonal antibodies as the active agent.

Group IX, claim(s) 37, drawn to a method of cleaning biological preparations.

Group X, claim(s) 38, drawn to a method of preventing prion disease using the prion protein as the active agent.

\*Note claim 39 will be examined to the extent that it reads on elected Group VIII or X.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-X appears to be the monoclonal antibody to prion protein. Kascsak et al. (The role of antibodies to PrP in the diagnosis of transmissible spongiform encephalopathies. Dev Biol Stand. 1993;80:141-51.) identify the production of monoclonal antibodies to detect prion protein. Therefore, the technical feature linking the inventions of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of group I is considered to be the monoclonal antibody to prion protein.

The special technical feature of group II is considered to be the anti-idiotypic antibody to prion protein.

The special technical feature of group III is considered to be a phage display of the monoclonal antibody to prion protein.

The special technical feature of group IV is considered to be the recombinant prion protein.

The special technical feature of group V is a method of producing a hybridoma cell line.

The special technical feature of group VI is a method of producing an expression vector.

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The special technical feature of group VII is an immunological detection method and a test kit.

The special technical feature of group VIII is a method of preventing prion disease.

The special technical feature of group IX is a method of cleaning biological samples.

The special technical feature of group X is a method of preventing prion disease using the prion protein as an active ingredient.

Accordingly, groups I-X are not so linked by the same or corresponding technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

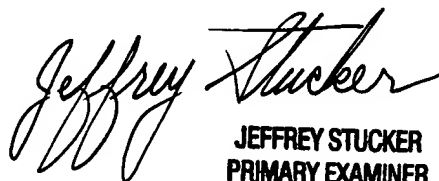
The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
**JEFFREY STUCKER**  
**PRIMARY EXAMINER**